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Form PTO - 1449 (Modified)

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE  
(Modified) PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use several sheets if necessary)

(37 CFR 1.98 (b))

ATTY. DOCKET NO.

6488.US.02

SERIAL NO.

09/709,829

APPLICANT

James J. Fort, *et al.*

FILING DATE

November 10, 2000

GROUP

1654

U.S. PATENT DOCUMENTS

EXAM. INITIAL		PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUB CLASS	FILING DATE
/JER/	A1	4,769,235	09/06/1988	Panoz, <i>et al.</i>			
	A2	4,904,699	02/27/1990	Bauer			
	A3	5,525,628	08/13/1996	Deboeck, <i>et al.</i>			
	A4	5,541,206	07/30/1996	Kempf, <i>et al.</i>			
	A5	5,648,497	07/15/1997	Kempf, <i>et al.</i>			
	A6	5,741,519	04/21/1998	Rosenberg, <i>et al.</i>			
	A7	5,773,025	06/30/1998	Baichwal			
	A8	5,889,051	03/30/1999	Chen, <i>et al.</i>			
	A9	5,914,332	06/22/1999	Sham, <i>et al.</i>			
	A10	5,939,099	08/17/1999	Grabowski, <i>et al.</i>			
	A11	5,948,426	09/07/1999	Al-Razzak, <i>et al.</i>			
	A12	6,027,747	02/22/2000	Terracol, <i>et al.</i>			
	A13	6,294,192	09/25/2001	Patel, <i>et al.</i>			
	A14	6,383,471	05/07/2002	Chen, <i>et al.</i>			
	A15	6,451,339	09/17/2002	Patel, <i>et al.</i>			
	A16	6,462,093	10/08/2002	Miyamoto, <i>et al.</i>			
	A17	6,608,198	08/19/2003	Dickman, <i>et al.</i>			
	A18	6,692,767	02/17/2004	Burnside, <i>et al.</i>			
	A19	6,730,319	05/04/2004	Maeder, <i>et al.</i>			
	A20	6,733,781	05/11/2004	Abu-Izza, <i>et al.</i>			
	A21	6,834,310	12/21/2004	Munger, <i>et al.</i>			
	A22	7,014,810	03/21/2006	Krull, <i>et al.</i>			
	A23	7,148,359	12/12/2006	Chemburkar, <i>et al.</i>			
	A24	7,229,641	06/12/2007	Cherukuri			

U.S. PATENT APPLICATION DOCUMENTS

EXAM. INITIAL		PATENT NUMBER	PUB. DATE	PATENTEE	CLASS	SUB CLASS	FILING DATE
/JER/	A25	2002/0006443	01/17/2002	Curatolo, <i>et al.</i>			
	A26	2003/0054038	03/20/2003	Crew, <i>et al.</i>			
	A27	2005/0048112	03/03/2005	Breitenbach, <i>et al.</i>			
	A28	2005/0084529	04/21/2005	Rosenberg, <i>et al.</i>			
	A29	2005/0143404	06/30/2005	Rosenberg, <i>et al.</i>			

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	<b>APPLICANT</b> James J. Fort, <i>et al.</i>	
	<b>FILING DATE</b> November 10, 2000	<b>GROUP</b> 1654

## FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

EXAM. INITIAL		DOCUMENT NUMBER	PUBLI- CATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUB CLASS	TRANSLATION	
							YES	NO
/JER/	B1	2 343 234	16.03.2000	CA				
	B2	2 352 874	08.06.2000	CA				
	B3	2 367 020	21.09.2000	CA				
	B4	2 368 625	05.10.2000	CA				
	B5	2 374 931	11.01.2001	CA				
	B6	2 479 749	02.10.2003	CA				
	B7	2,501,245	22.04.2004	CA				
	B8	2 568 378	08.12.2005	CA				
	B9	0 414 422	27.02.1991	EP				
	B10	0 732 923	12.12.2001	EP				
	B11	0 852 140	03.12.2003	EP				
	B12	0 864 324	16.09.1998	EP				
	B13	0 864 326	16.09.1998	EP				
	B14	0 942 721	22.01.2003	EP				
	B15	0 988 106	29.03.2000	EP				
	B16	2 053 681	11.02.1981	GB				
	B17	90/06115	14.06.1990	WO				X
	B18	95/22319	24.08.1995	WO				
	B19	95/07696	23.03.1995	WO				
	B20	95/09614	13.04.1995	WO				
	B21	97/06781	27.02.1997	WO				X
	B22	97/46222	11.12.1997	WO				
	B23	98/22106	28.05.1998	WO				
	B24	98/24430	11.06.1998	WO				
	B25	00/57854	04.10.2000	WO				
	B26	00/74677	14.12.2000	WO				
	B27	01/00175	04.01.2001	WO				
	B28	01/22938	05.04.2001	WO				
	B29	01/23362	05.04.2001	WO				
	B30	01/34118	17.05.2001	WO				
	B31	01/34119	17.05.2001	WO				
	B32	01/52821	26.07.2001	WO				
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	B34	02/20057	14.03.2002	WO				
	B35	02/096395	05.12.2002	WO				

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT James J. Fort, <i>et al.</i>	
(Use several sheets if necessary)	FILING DATE November 10, 2000	GROUP 1654

(37 CFR 1.98 (b))

## FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

/JFR/	B36	02/092595	21.11.2002	WO				
	B37	03/080120	02.10.2003	WO				
	B38	2004/039349	13.05.2004	WO				
	B39	2004/050068	17.06.2004	WO				
	B40	2004/054568	01.07.2004	WO				
	B41	2005/004836	20.01.2005	WO				
	B42	2005/007139	27.01.2005	WO				

## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

EXAM. INITIAL		
/JFR/	C1	Aungst, B.J., <i>et al.</i> , "Improved Oral Bioavailability of an HIV Protease Inhibitor Using Gelucire 44/14 and Labrasol Vehicles", <i>B.T. Gattefosse</i> , 87:49-54 (1994)
	C2	Awni, W., <i>et al.</i> , "Significantly Reduced Food Effect and Pharmacokinetic Variability with a Novel Lopinavir/Ritonavir Tablet Formulation", <i>third IAS Conf. On HIV Pathogenesis and Treatment</i> , (2005)
	C3	BASF Fine Chemicals, "ExAct Excipients & Actives for Pharma", BASF, 2:1-16 (1999)
	C4	Bouma, M.G., <i>et al.</i> , "Novel Therapeutic Delivery Systems", <i>J. of Contr. Rel.</i> , 87:199-308 (2003)
	C5	Breitenbach, J., "Melt Extrusion Can Bring New Benefits to HIV Therapy: The Example of Kaletra (R) Tablets", <i>Amer. J. of Drug Deliv.</i> , 4(2):61-64 (2006)
	C6	Breitenbach, J., "Melt extrusion: from process to drug delivery technology", <i>Eur. J. of Pharm. &amp; Biopharm.</i> , 54:107-117 (2002)
	C7	Chiou, W.L. & Riegelman, S., "Pharmaceutical Applications of Solid Dispersion Systems", <i>J. of Pharm. Sci.</i> , 60(9):1281-1301 (1971)
	C8	Corrigan, I.I. & Healy, A.M., "Surfactants in Pharmaceutical Products and Systems", <i>Encycl. Of Pharm. Tech.</i> , 2639-2653 (2002)
	C9	Ford, J.L., "The Current Status of Solid Dispersions", <i>Pharm. Acta Helv.</i> , 61(3):69-88 (1986)
	C10	Forster, A., <i>et al.</i> , "Selection of excipients for melt extrusion with two poorly water-soluble drugs by solubility parameter calculation and thermal analysis", <i>Intn'l J. of Pharm.</i> , 226:147-161 (2001)
	C11	Hulsmann, S., <i>et al.</i> , "Melt extrusion - an alternative method for enhancing the dissolution rate of 17 $\beta$ -estradiol hemihydrate", <i>Eur. J. of Pharm. &amp; Biopharm.</i> , 49:237-242 (2000)
	C12	International Search Report & Written Opinion from PCT/US2004/027401 dated May 8, 2006
	C13	Karanth, H., <i>et al.</i> , "Industrially Feasible Alternative Approaches in the Manufacture of Solid Dispersions: A Technical Report", <i>AAPS PharmSciTech</i> , 7(4):Art. 87 (2006)
	C14	Law, D., <i>et al.</i> , "Physicochemical Considerations in the Preparation of Amorphous Ritonavir-Poly(ethylene glycol) 8000 Solid Dispersions", <i>J. of Pharm. Sci.</i> , 90(8):1015-1025 (2001)

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## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

EXAM. INITIAL		
/JER/	C15	Law, D., <i>et al.</i> , "Ritonavir-PEG 8000 Amorphous Solid Dispersions: <i>In Vitro</i> and <i>In Vivo</i> Evaluations", <i>J. of Pharm. Sci.</i> , 93(3):563-570 (2004)
	C16	Palmieri, G.F., <i>et al.</i> , "Characterization and dissolution studies of PEG 4000/fenofibrate solid dispersions", <i>S.T.P. Pharma Sci.</i> , 6(3):188-194 (1996)
	C17	Physicians Desk Reference, online excerpt, PDR Electronic Library (not dated)
	C18	Physicians Desk Reference, online ... Norvir, Fenofibrate, and Greiseosulvin (not dated)
	C19	Serajuddin, A.T.M., "Solid Dispersion of Poorly Water-Soluble Drugs: Early Promises, Subsequent Problems and Recent Breakthroughs", <i>J. of Pharm. Sci.</i> , 88(10):1058-1066 (1999)
	C20	U.S. Patent Application 09/438,994, James J. Fort, <i>et al.</i> , filed November 12, 1999
	C21	U.S. Patent Application 11/691,819, James J. Fort, <i>et al.</i> , filed March 27, 2007
	C22	U.S. Patent Application 11/773,185 Joerge Rosenberg, <i>et al.</i> , filed July 3, 2007
	C23	Zhu, T., <i>et al.</i> , "New Tablet Formulation of Lopinavir/Ritonavir is Bioequivalent to the Capsule at a Dose of 800/200 mg", 48 <sup>th</sup> Int. Conf. On Antimic. Agents & Chem., (ICAAC), (2005)

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